DEPARTMENT OF HEALTH & HUMAN SERVICES

T1394M

Certified - Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

December 9, 1997

WARNING LETTER

Michael G. Hamik, President & CEO
Med-Pro, Inc.
210 East 4th Street
Lexington, Nebraska 68850

Ref.# - KAN-98-004

Dear Mr. Hamik:

During an inspection of your drug repackaging facility, located at the above address, conducted February 18 through 25, 1997, a Food and Drug Administration Investigator from this office observed the drug processing identified as *"overpackaging"*. This particular repackaging process is the focus of this letter. In this contract repackaging process, unit-dose drug products are removed from their marketed packages and separated into individual units which are then repackaged individually into labeled plastic bags, heat sealed and boxed for shipment to the contracting firm.

We have reviewed the labeling of the drug products repackaged in this operation and have concluded that these drug products are misbranded within the meaning of Section 502(c) of the Federal Food, Drug, and Cosmetic Act, because all the information required to appear on the label or labeling is not present as discussed herein.

In general, the label of the immediate container of drug products is of sufficient size to include all the required label information. This same label information is also required to appear on the outside containers or wrappers, when such secondary packaging is used.

In the case of drugs packaged as unit-dose products, the immediate container, i.e., the unit-dose container, is usually too small to accommodate all required label information. Because of their small size, the label of unit-dose containers is ordinarily exempted from bearing all required label content. However, all required label content is to be present on the carton or other outer container or wrapper of unit-dose products.

For the unit-dose products that you repackage, the original carton bears all the required label content that the unit-dose containers

lack due to their small size. However, as determined by the inspection, the labeling that is present on the container or wrapper and the labeling on the carton for the products that you repackage does not include all the required label content.

Specifically, the labeling does not include the following:

> The statement: "Caution: Federal law prohibits dispensing without prescription."
>
> A statement of the recommended or usual dosage or a statement such as "See package insert for dosage information."

Please note that the "FDA Modernization Act of 1997" enacted on November 21, 1997 revises the requirement for the "Caution" statement noted above, allowing for, at a minimum, the symbol "Rx only". The specific statement quoted in the offset text above, also meets this requirement.

It is noted that the labeling also does not include a declaration of the quantity of contents. Although this may not be necessary for the individual units of repackaged drug products when their original label includes such a statement on it, and the total contents are fully visible through the repackaging bag, the carton label needs to include a declaration of the quantity of contents.

It is also noted that the labeling of repackaged Prednisone 10 mg tablets, Lot 961423, identified the name and place of business of your company without any qualification. The appearance on a drug product label of a person's name without qualifications is a representation that the named person is the sole manufacturer of the product.

Further, it is noted that within the labeling of repackaged Heparin Sodium 5000 units/0.5 ml Injection, Lot 2960305, your company's name is qualified by the expression *"Overpackaged by."* Although this expression may be understood by the purchasers of these products, it is not one identified in the regulation that directs drug product label qualification of persons named on the label, i.e., "Packed by" or "Packaged by" [Title 21 Code of Federal Regulations, Part 201.1(h)(6)].

As described in the report of the inspection, the original package insert is included within the box. This is acceptable, provided the box is not subdivided prior to delivery to the pharmacy.

Please be advised that the labeling of the drug products you repackage should include any storage condition information present on the original product label.

The above identification of deficiencies may not be all inclusive, nor are they intended to be a complete review of the labeling of all your products. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. You

should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

/S/

W. Michael Rogers
District Director
Kansas City District

cc: [redacted]

Copy: Related Firm
DISTRIBUTION:
Orig.: Addressee
bcc: LF; FF(1930466); HFA-224; HFD-333(S. Crisp); HFI-35/DIB(via FOI); HFC-210; HFC-240(MPQAS); O/RP; SAN-DO(HFR-PA140); GDD; WMR(chrono); RF

CRP:jl